

K053426 ROCHE ELECSYS ANTI-TGFeb 7, 2006
61 days to decisionK053426 · Product code: **JZO** · Immunology
Source: <https://www.510kdatabase.net/k053426/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Thyroid Autoantibody (JZO)
Date received	Dec 8, 2005
Decision date	Feb 7, 2006
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	RANDY JOHNSON
510(k) history	264 submissions · 263 cleared · 1999-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053426/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 9, 2026